

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)
FENFLURAMINE/DEXFENFLURAMINE)) MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)

) THIS DOCUMENT RELATES TO:)
) SHEILA BROWN, et al.) CIVIL ACTION NO. 99-20593
v.)
) AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)
)

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8215

Bartle, C.J

July 1 , 2009

Phyllis Mire ("Ms. Mire" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Lloyd Mire, Ms. Mire's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See (continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. Part I of the Green Form is to be completed by the claimant or the claimant's representative. Part II is to be completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In May 2003, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Paul Nathan, M.D. Based on an echocardiogram dated October 10, 2002, Dr. Nathan attested in Part II of Ms. Mire's Green Form that she suffered from severe mitral regurgitation and an abnormal left atrial

3 (...continued)

Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

dimension.⁴ Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$467,536.⁵

In the report of claimant's echocardiogram, Dr. Nathan stated that: "[c]olor flow and Doppler examination reveals severe mitral regurgitation with left atrial area regurgitant jet area percentage of 47%." Under the definition set forth in the Settlement Agreement, severe mitral regurgitation is present where the Regurgitant Jet Area ("RJA"), in any apical view, is greater than 40% of the Left Atrial Area ("LAA"). See Settlement Agreement §§ I.22 & IV.B.2.c.(2)(b).⁶ Dr. Nathan also stated that claimant has "mild left atrial enlargement." The Settlement Agreement defines an abnormal left atrial dimension as a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view or a left atrial antero-posterior

4. Initially, Dr. Nathan also attested that claimant has an ejection fraction in the range of 50% to 60%. Dr. Nathan, however, later revised his answer to reflect that claimant does not have this condition. Accordingly, we need not address whether claimant had a reduced ejection fraction.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement IV.B.2.c.(2)(b). As the Trust concedes that there is a reasonable medical basis for finding that claimant has moderate mitral regurgitation, the only issue is whether claimant has an abnormal left atrial dimension.

6. Pursuant to the Settlement Agreement, moderate or greater mitral regurgitation is present where the RJA in any apical view is equal to or greater than 20% of the LAA. Id.

systolic dimension greater than 4.0 cm in the parasternal long axis view. See id. § IV.B.2.c.(2)(b).

In November 2003, the Trust forwarded the claim for review by Eduardo Antonio Arazoza, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Arazoza concluded that there was no reasonable medical basis for Dr. Nathan's finding that claimant has severe mitral regurgitation. According to Dr. Arazoza: "[t]he color Doppler is of poor quality and overestimates the size of the MR jet. Planimetry is also poor. The MR appears to be mild." In the Report of Auditing Cardiologist Opinions Concerning Green Form Questions At Issue, however, Dr. Arazoza stated that claimant has moderate mitral regurgitation.⁷ In addition, Dr. Arazoza concluded that there was no reasonable medical basis for finding an abnormal left atrial dimension because: "[t]he m-mode measurement of the LA is incorrect. The parasternal measurement goes outside of the LA and is an overestimation of the LA size. The LA is not enlarged."

Based on the auditing cardiologist's diagnoses, the Trust issued a post-audit determination denying Ms. Mire's claim.

7. We need not resolve the discrepancy between Dr. Arazoza's conflicting statements about claimant's level of mitral regurgitation because the Trust concedes that there is a reasonable medical basis for finding that claimant has moderate mitral regurgitation.

Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁸

In contest, claimant submitted a declaration from Jack Schwade, M.D., who supported the attesting physician's findings of moderate mitral regurgitation and an abnormal left atrial dimension.⁹ In his declaration, Dr. Schwade stated, in pertinent part, that: (1) claimant's mitral valve regurgitation was "greater than 20%, which qualifies as moderate mitral regurgitation under the Singh Protocol;" and (2) claimant's left atrial antero-posterior systolic dimension was greater than 4.0 cm in the parasternal long-axis view and that the left atrial supero-inferior systolic dimension was greater than 5.3 cm in the apical four-chamber view.¹⁰

Based on claimant's contest, the Trust submitted the claim to Dr. Arazoza for a second review. Dr. Arazoza prepared a declaration, confirming his previous conclusion that there was no

8. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Mire's claim.

9. Dr. Schwade attached to his declaration four still frames from claimant's echocardiogram.

10. In contest, claimant also submitted an excerpt from previous testimony of Richard Dent, M.D. Claimant, however, did not explain how this testimony was relevant to her claim.

reasonable medical basis for Dr. Nathan's findings of severe mitral regurgitation or an abnormal left atrial dimension. Specifically, Dr. Arazoza stated that:

In accordance with the Trust's request, I reviewed the claim, including the entirety of Claimant's echocardiogram tape, for a second time. I again concluded that Claimant's level of mitral regurgitation is moderate in real time. In her contest materials, Claimant's expert, Jack Schwade, M.D., also agreed that Claimant has moderate mitral regurgitation.

I also again concluded that Claimant's left atrial dimensions are normal. Claimant's Attesting Physician and expert relied upon a measurement of the parasternal long axis view, which was improperly made tangentially in the M-mode. The line was drawn on a diagonal and went into the wall of the atrium off the aorta. Claimant's Attesting Physician and expert clearly relied on an inflated measurement.

All of my measurements of the left atrial dimensions were under 4.0 cm in the parasternal long axis view and under 5.3 cm in the apical 4-chamber view.

The Trust then issued a final post-audit determination, denying Ms. Mire's claim for lack of a reasonable medical basis to support the attesting physician's finding of an abnormal left atrial dimension. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause

why Ms. Mire's claim should be paid. On October 19, 2004, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 4034 (Oct. 19, 2004).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on June 1, 2005. Claimant was granted permission to submit a sur-reply dated June 30, 2005. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor¹¹ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, James F. Burke, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor's Report are now before the court for final determination. See id. Rule 35.

11. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposition positions" is proper. Id.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding of an abnormal left atrial dimension. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Mire argues, among other things, that Dr. Schwade's declaration provides a reasonable medical basis for the finding that she had an abnormal left atrial dimension.¹² Claimant also argues that: (1) the phrase "reasonable medical basis" is a fluid term, which incorporates inter-reader variability; (2) reasonable medical basis does not mean that the auditing cardiologist has to reach the same conclusion as the attesting physician; (3) the auditing cardiologist's opinion is inadmissible because it fails to

12. The Special Master also permitted claimant to submit a supplemental declaration of Dr. Schwade, in which he again asserted his opinion that claimant has an abnormal left atrial dimension.

explain the lack of a reasonable medical basis; and (4) the Trust's conduct amounts to a violation of claimant's due process rights. In support of her last argument, claimant submitted a report of Dr. Khatab M. Hassanein and Dr. Ruth S. Hassanein, which analyzed data from the Trust concerning audits.

In response, the Trust primarily asserts that claimant failed to establish a reasonable medical basis for the attesting physician's finding of an abnormal left atrial dimension. The Trust further argues that: (1) claimant's characterization of the reasonable medical basis standard is incorrect; (2) claimant's inter-reader variability argument does not refute the auditing cardiologist's conclusions; (3) the auditing cardiologist followed the Audit Rules and the Settlement Agreement; and (4) claimant's due process argument must fail because the Audit Rules provide adequate notice and an opportunity to be heard.¹³

The Technical Advisor, Dr. Burke, reviewed claimant's echocardiogram and concluded that there was a reasonable medical

13. In its show cause submissions, the Trust also argues that Federal Rule of Civil Procedure 26(a)(2) requires physicians who proffer opinions regarding claims to disclose their compensation for reviewing claims and provide a list of cases in which they have served as experts. Claimant's sur-reply responds directly to this argument. As we previously have stated, Rule 26(a)(2) disclosures are not required under the Audit Rules. See PTO No. 6996 (Feb. 26, 2007).

basis for the attesting physician's finding of an abnormal left atrial dimension.¹⁴ Specifically, Dr. Burke found that:

I thought the left atrium was dilated. I measured a dimension of 41 mm in diameter in the parasternal long axis view and a measurement of 58 mm in the superoinferior measurement in the apical four chamber view. These measurements are both outside the normal range and compatible with left atrial enlargement.

I believe there is a reasonable medical basis for the Attesting Physician's answer to Green Form Question F.5., which states that Claimant has an abnormal left atrial dimension. An echocardiographer could reasonably conclude that the echocardiogram dated 10/10/02 indicates that this Claimant has an abnormal left atrial dimension.

After reviewing the entire Show Cause Record before us, we find that claimant has established a reasonable medical basis for her claim. Claimant's attesting physician, Dr. Nathan, found that claimant has an abnormal left atrial dimension. Although the Trust contested the attesting physician's conclusion, Dr. Burke confirmed the attesting physician's finding of an abnormal left atrial dimension.¹⁵ Specifically, Dr. Burke stated that "there is a reasonable medical basis for the Attesting

14. Dr. Burke also found that there was a reasonable medical basis for concluding that claimant has moderate mitral regurgitation.

15. Despite an opportunity to do so, the Trust did not submit any response to the Technical Advisor Report. See Audit Rule 34.

Physician's answer . . . that Claimant has an abnormal left atrial dimension."

As stated above, a left atrial dimension is considered abnormal where a left atrial supero-inferior systolic dimension is greater than 5.3 cm in the apical four chamber view or a left atrial antero-posterior systolic dimension is greater than 4.0 cm in the parasternal long axis view. See Settlement Agreement § IV.B.2.c.(2)(b). Here, Dr. Burke measured claimant's left atrial dimension as 58 mm (or 5.8 cm) in the apical four chamber view and 41 mm (or 4.1 cm) in the parasternal long axis view. Under these circumstances, claimant has met her burden in establishing a reasonable medical basis for her claim. Accordingly, we need not address claimant's remaining arguments.

For the foregoing reasons, we conclude that claimant has met her burden in proving that there is a reasonable medical basis for her claim and is consequently entitled to Matrix A-1, Level II benefits. Therefore, we will reverse the Trust's denial of the claims submitted by Ms. Mire and her spouse for Matrix Benefits.